



PTO/SB/08a/b (07-05)
Approved for use through 07/31/2008. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete If Known		
			Application Number	09/827428-Conf. #6098	
			Filing Date	April 6, 2001	
			First Named Inventor	Orlow	
			Art Unit	1614	
			Examiner Name	Lewis	
Sheet	1	of	1	Attorney Docket Number	0071369.00162US3/PFI-016CIP

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ -Number-Kind Code ⁵ (if known)				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/A.S./	CA	SEIBERG et al., Inhibition of Melanosome Transfer Results in Skin Lightening, J. Invest. Dermatol., 2000, v. 115, pp. 162-167	

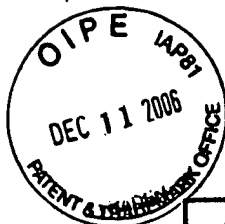
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
-----------------------	---------------	--------------------	------------

5351488

US1DOCS 5741823v1



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/827,428-Conf. #6098
Filing Date		April 6, 2001			
First Named Inventor		Seth J. ORLOW			
Art Unit		1614			
Examiner Name		A. A. Lewis			
Attorney Docket Number		0071369.00162US3/PFI-016CIP			
Sheet	1	of	3		

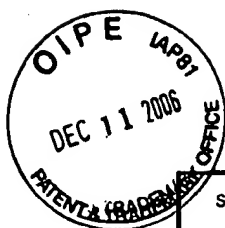
U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/A.S./	AA*	US-5,628,987	05-13-1997	Fuller	
/A.S./	AB*	US-5,686,103	11-11-1997	Redziniak et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			
/A.S./	BA	WO-01/01131	01-04-2001	Univ New York		
/A.S./	BB	WO-97/00892	01-09-1997	Us Health et al.		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
/A.S./	CA	ABDEL-MALEK, et al., "Mitogenic, Melanogenic and cAMP Responses of Cultured Neonatal Human Melanocytes to Commonly Used Mitogens", Journal of Cellular Physiology, 150:416-425 (1992)		
	CB	ANCANS, et al., "Activation of Melanogenesis by Vacuolar Type H ⁺ -ATPase Inhibitors in Amelanotic, Tyrosinase Positive Human and Mouse Melanoma Cells", FEBS Letters, 478:57-60 (2000)		
	CC	ANSEL, et al., <u>Pharmaceutical Dosage Forms and Drug Delivery Systems</u> , Sixth Ed., A Lea & Febiger Book, Williams & Wilkins, Baltimore (1995)		
	CD	BOUCHARD, et al., "Induction of Pigmentation in Mouse Fibroblasts by Expression of Human Tyrosinase cDNA", J. Exp. Med., 169:2029-2042 (1989)		
	CE	BRILLIANT, et al., "Anatomy of Pigment Cell Genes Acting at the Cellular Lever", in <u>The Pigmentary System: Physiology and Pathophysiology</u> , Norlund, et al., eds., Oxford University Press, Chapter 18, pp. 217-229 (1998)		
	CF	CHAKRABORTY, et al., "Effect of Arbutin on Melanogenic Proteins in Human Melanocytes", Pigment Cell Research, 11:206-212 (1998)		
	CG	GARDNER, et al., "The Complete Nucleotide Sequence of an Infectious Clone of Cauliflower Mosaic Virus by M13mp7 Shotgun Sequencing", Nucleic Acids Research, 9(12):2871-2888 (1981)		
	CH	GILBERT, et al., "Useful Proteins from Recombinant Bacteria", Sci. Am., 242(4):74-94 (1980)		
	CI	HALL, et al., "Accumulation of Tyrosinase in the Endolysosomal Compartment in Induced by U18666A", Pigment Cell Res., 16:149-158 (2003)		

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
--------------------	---------------	-----------------	------------



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0851-0031

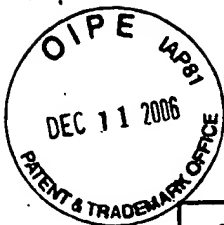
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	09/827,428-Conf. #6098
				Filing Date	April 6, 2001
				First Named Inventor	Seth J. ORLOW
				Art Unit	1614
				Examiner Name	A. A. Lewis
				Attorney Docket Number	0071369.00162US3/PFI-016CIP
Sheet	2	of	3		

/A.S./	CJ	HARLOW, et al., <u>Antibodies - A Laboratory Manual</u> , Cold Spring Harbor Laboratory (1988) (cover of book and page (i))	
	CK	HU, et al., "Regulation of Melanogenesis by Human Uveal Melanocytes In Vitro", <u>Exp. Eye Res.</u> , 64:397-404 (1997)	
	CL	IMOKAWA, et al., "Skin Organ Culture Model for Examining Epidermal Melanization", <u>Journal of Investigative Dermatology</u> , 100:47-54 (1993)	
	CM	JIMENEZ, et al., "Tyrosinases from Two Different Loci are Expressed by Normal and by Transformed Melanocytes", <u>Journal of Biological Chemistry</u> , 266(2):1147-1156 (1991)	
	CN	KIM, et al., "Expression of a Thioredoxin-Related Protein-1 is Induced by Prostaglandin E ₂ ", <u>Int. J. Cancer</u> , 118:1670-1679 (2006)	
	CO	KUZUMAKI, et al., "Eumelanin Biosynthesis is Regulated by Coordinate Expression of Tyrosinase and Tyrosinase-Related Protein-1 Genes", <u>Experimental Cell Research</u> , 207:33-40 (1993)	
	CP	LERNER, et al., "Biochemistry of Melanin Formation", <u>Physiol. Rev.</u> , 30(1):91-126 (1950)	
	CQ	MACDONALD, "Expression of the Pancreatic Elastase I Gene in Transgenic Mice", <u>Hepatology</u> , 7(1):42S-51S (1987)	
	CR	MASON, et al., "The Hypogonadal Mouse: Reproductive Functions Restored by Gene Therapy", <u>Science</u> , 234(4782):1372-1378 (1986)	
	CS	MCCURDY, "Enzyme Localization During Melanogenesis", <u>Journal of Cell Biology</u> , 48:220-228 (1969)	
	CT	NIEKRASZ, et al., "The Pig as Organ Donor for Man", <u>Transplantation Proceedings</u> , 24(2):625-626 (1992)	
	CU	OETTING, et al., "Mutations of the Human P Gene Associated with Type II Oculocutaneous Albinism (OCA2)", <u>Human Mutation</u> , 12(6):434 (1998)	
	CV	ORLOW, "The Biogenesis of Melanosomes", in <u>The Pigmentary System: Physiology and Pathophysiology</u> , Norlund, et al., eds, Oxford University Press, Chapter 6, pp. 97-106 (1998)	
	CW	ORLOW, et al., "Retinoic Acid is a Potent Inhibitor of Inducible Pigmentation in Murine and Hamster Melanoma Cell Lines", <u>Journal of Investigative Dermatology</u> , 64(4):461-464	
	CX	ORNITZ, et al., "Elastase I Promoter Directs Expression of Human Growth Hormone and SV40 T Antigen Genes to Pancreatic Acinar Cells in Transgenic Mice", <u>Cold Spring Harb. Symp. Quant. Biol.</u> , 50:399-409 (1985)	
	CY	PINKERT, et al., "An Albumin Enhancer Located 10 kb Upstream Functions Along with Its Promoter to Direct Efficient, Liver-Specific Expression in Transgenic Mice", <u>Genes & Development</u> , 1:268-276 (1987)	
	CZ	Product Information Sigma: Composition of the Medium Ham's F10	
	CA1	Product Information Sigma: Composition of the Medium MCDB-153	
	CB1	<u>Remington's Pharmaceutical Sciences</u> , 18th Edition, Alfonso Gennaro, Editor, Mack Publishing Company, Easton, PA (1990)	
	CC1	SAKAI, et al., "Modulation of Murine Melanocyte Function <i>in vitro</i> by Agouti Signal Protein", <u>EMBO Journal</u> , 16(12):3544-3552 (1997)	
	CD1	SCHWARTZ, et al., <u>Surface Active Agents, Their Chemistry and Technology</u> , Interscience Publishers, Inc, New York, NY (1949)	
	CE1	SEIJI, et al., "Subcellular Localization of Melanin Biosynthesis", <u>Ann. NY Acad. Sci.</u> , 100:497-533 (1963)	
	CF1	SHANI, "Tissue-Specific Expression of Rat Myosin Light-Chain 2 Gene in Transgenic Mice", <u>Nature</u> , 314:283-286 (1985)	

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
--------------------	---------------	-----------------	------------



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/827,428-Conf. #6098
				Filing Date	April 6, 2001
				First Named Inventor	Seth J. ORLOW
				Art Unit	1614
				Examiner Name	A. A. Lewis
Sheet	3	of	3	Attorney Docket Number	0071369.00162US3/PFI-016CIP

/A.S./	CG1	YOKOYAMA, et al., "Conserved Cysteine to Serine Mutation in Tyrosinase is Responsible for the Classical Albino Mutation in Laboratory Mice", Nucleic Acids Research, 18(24):7293-7298 (1990)	
--------	-----	--	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*Applicant's unique citation designation number (optional). *Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
-----------------------	---------------	--------------------	------------



PTO/SB/08A/B (09-06)
Approved for use through 03/31/2007. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete If Known		
			Application Number	09/827,428-Conf. #6098	
			Filing Date	April 6, 2001	
			First Named Inventor	Seth J. ORLOW	
			Art Unit	1614	
			Examiner Name	A. A. Lewis	
Sheet	1	of	1	Attorney Docket Number	PFI-016CIP/291472-124US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/A.S./	AA*	US-4,439,432	03-27-1984	Peat	
✓	AB*	US-5,569,678	10-29-1996	Lee	
	AC*	US-5,616,332	04-01-1997	Herstein	

FOREIGN PATENT DOCUMENTS						
Examiner Initials *	Cite No. ¹	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY			

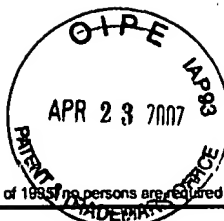
*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
-----------------------	---------------	--------------------	------------



PTO/SB/08A/B (09-06)

Approved for use through 03/31/2007. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO				Complete If Known	
				Application Number	09/827,428-Conf. #6098
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Filing Date	April 6, 2001
				First Named Inventor	Seth J. ORLOW
				Art Unit	1614
				Examiner Name	A. A. Lewis
Sheet	1	of	1	Attorney Docket Number	PFI-016CIP (291472.124US1)

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.18 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
/A.S./	CA	BOROVANSKY, et al., "Melanogenesis in Transfected Fibroblasts Induces Lysosomal Activation", Arch Dermatol. Res., 289:145-150 (1997)			
	CB	DENNELL, "Weismann's Ring and the Control of Tyrosinase Activity in the Larva of Calliphora Erythrocephala", Proceedings of the Royal Society of London, 136(882):94-109 (1949)			
	CC	IMOKAWA, "Analysis of Initial Melanogenesis Including Tyrosinase Transfer and Melanosome Differentiation Through Interrupted Melanization by Glutathione", Journal of Investigative Dermatology, 93(1):100-107 (1989)			
	CD	PALUMBO, et al., "Subcellular Localization and Function of Melanogenic Enzymes in the Ink Gland of Sepia Officinalis", Biochem J., 323:749-756 (1997)			

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Ali Soroush/	Date Considered	10/28/2007
-----------------------	---------------	--------------------	------------